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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/506,838 02/18/00 BRITTO

I 2801-136P

HM12/0905
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EXAMINER

BAWA, R

ART UNIT

PAPER NUMBER

1619

DATE MAILED:

09/05/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/506,838

Applicant(s)

Britto

Examiner

Mr. Raj Bawa

Group Art Unit

1619

- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 22-35 and 37-51 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 22-35 and 37-51 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of References Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1619

Detailed Action

(1) The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

(2) Claims of this application conflict with claims of Application No. 08/945,141 and 09/506,834. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

(3) Claims 22-35 and 37-51 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The recitation in the claims of (i) 0.0001%-50% wt. surfactant (page 3) ; (ii) propellants being P-134a or P-227 (page 4); (iii) the fluorocarbon polymers being PTFE, PE, PFA, ETFE or PVDF (page 4); (iv) the drug particle size being less than 100 microns (page 5); (v) 0.005-5% wt. drug (page 5); and (vi) 10u-50u coating thickness of the fluorocarbon polymer are features that are critical or essential to the practice of the invention, but are not included in the claim(s). Hence, the claims are is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The above-mentioned limitations are not preferred embodiments of the present invention but are critical limitations. Hence, in the absence of the above limitations, "undue experimentation" would be required by the ordinary worker to

Art Unit: 1619

practice the claimed invention. Claims are read in light of the specification, and the claims in this case are not commensurate in scope with the specification in the absence of these limitations.

(4) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22-35 and 37-51 are rejected under 35 U.S.C. § 103 as being unpatentable over Evans et al. (USP 5,261,538) and Gennaro.

Evans et al. disclose a MDI which contains the claimed drug aerosol formulation (see claims, abstract).

Art Unit: 1619

Gennaro discloses that aerosol containers are routinely coated with organic materials on the inside of the container (page 1670). The cited art lacks a specific disclosure of the fluoropolymers claimed. The use of surfactants in MDIs is conventional. All ingredients of the claimed aerosol are well known in the drug aerosol art. Hence, it would be prima facie obvious to one of ordinary skill in the art at the time of the invention to coat the inside of the MDI of Evans (that contains the claimed aerosol) with a polymer such as Teflon and obtain the claimed metered dose inhaler. The motivation to do so arises from the fact that (i) Gennaro clearly discloses the use of such organic polymer coats (plastics; epoxy; vinyl and phenolic resins) in MDIs; and (ii) such coats are routinely employed in the drug aerosol art to reduce adhesion of drug particles to the inside of the container. Hence, both the suggestion and the reasonable expectation of success in this case is found in the prior art cited.

Furthermore, note that "substantially free of surfactant" does not exclude the presence of a surfactant from the claimed aerosol. Combination of different classes of drugs in aerosols is not novel. The claimed MDI is conventional.

Note that: (i) the cited art is analogous because it pertains to the field of the inventor's endeavor and is also reasonably pertinent to the particular problem with which the inventor is involved. *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992); (ii) a comprising-type language does not exclude other steps, elements or materials. *Cues Inc. vs. Polymer Industries*, USPQ2d 1847 (DC ND GA 1988); (iii) it is well established that the claims are given the broadest interpretation during examination; (iv) a conclusion of obviousness under 35 U.S.C.

Art Unit: 1619

103(a) does not require absolute predictability, only a reasonable expectation of success; and (v) references are evaluated by what they suggest to tone versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 U.S.P.Q. 545 (CCPA 1969).

In light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been obvious within the meaning of 35 U.S.C. 103(a).

- (5) Please update the status of all continuation data referred to on page 1 of the specification.
- (4) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mr. Raj Bawa whose telephone number is (703) -308-2423. The examiner can normally be reached on Tuesday-Friday from 7:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash, can be reached on (703) -308-2328. The fax phone number for the organization where this application or proceeding is assigned is (703) -305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) -308-1235.

Bawa/LR

August 2, 2000



RAJ BAWA, Ph.D.
PRIMARY EXAMINER